

**IN THE CLAIMS:**

**Complete Listing and Status of the Claims**

1-195            Canceled

196. (New) A method of repairing or ameliorating urethra muscle tissue injury, damage, or dysfunction associated with stress urinary incontinence, comprising:

- (a) providing a population of undifferentiated muscle-derived cells (MDCs) capable of giving rise to diverse muscle cell types and comprising an end population of cells isolated by a method comprising:
  - (i) plating a suspension of muscle cells in a first container to which fibroblast cells adhere;
  - (ii) re-plating non-adherent cells from step (a) in a second container when approximately 15-20% of the cells from the cell suspension have adhered to the first container;
  - (iii) repeating step (ii) at least two times to enrich for an end population of viable, non-fibroblast, desmin-expressing cells in the second container; and
  - (iv) isolating the MDCs as the end population of viable, non-fibroblast, desmin-expressing cells; and
- (b) introducing the MDCs of step (a) into a site of injured, damaged, or dysfunctional urethra muscle tissue in an amount effective to repopulate and repair the injured, damaged, or dysfunctional urethra muscle tissue.

197. (New)            The method according to claim 196, wherein the MDCs are autologous to a recipient in need of treatment.

198. (New)            The method according to claim 196, wherein the MDCs are histocompatibly-matched with a recipient in need of treatment.

199. (New)            The method according to claim 196, wherein the MDCs are obtained from skeletal muscle tissue.

200. (New) The method according to claim 196, wherein MDCs are introduced in an amount of about  $10^5$  to  $10^6$  cells per  $\text{cm}^3$  of tissue to be treated in a physiologically acceptable medium.

201. (New) The method according to claim 196, further comprising culturing the MDCs obtained according to step (a) under conditions allowing for their proliferation, differentiation, or a combination thereof, prior to said introducing step (b).

202. (New) The method according to claim 196, wherein a cloned population of the MDCs obtained in step (a) is introduced into a recipient in need of treatment.

203. (New) The method according to claim 196, further wherein, subjecting the MDCs to a cytokine or growth factor selected from the group consisting of basic fibroblast growth factor (b-FGF), insulin-like growth factor (IGF), and nerve growth factor (NGF) prior to the introducing step (b) stimulates proliferation and myofiber fusion of the MDCs after introduction into the muscle tissue.

204. (New) The method according to claim 196, wherein the MDCs contain a heterologous polynucleotide encoding an IGF-1 cytokine or growth factor expressed by the MDCs.

205. (New) The method according to claim 204, wherein the MDCs are transduced with a viral vector containing the heterologous polynucleotide.

206. (New) The method according to claim 204, wherein the MDCs are transfected with plasmid DNA containing the heterologous polynucleotide.

207. (New) The method according to claim 205, wherein the viral vector is selected from the group consisting of adenovirus, herpes simplex virus, adeno-associated virus, and retrovirus.

208. (New) The method according to claim 203 or claim 204, further comprising introducing the same or different MDCs containing a heterologous

polynucleotide encoding interleukin-1 receptor antagonist protein immune suppression factor (IRAP).

209. (New) The method according to claim 196, wherein the MDCs contain a vector containing a heterologous polynucleotide encoding human inducible nitric oxide synthase (iNOS), wherein the inducible nitric oxide synthase (iNOS) is expressed by the MDCs.

210. (New) The method according to claim 209, wherein the MDCs are transduced with a replication-defective viral vector containing the heterologous polynucleotide encoding inducible nitric oxide synthase (iNOS).

211. (New) The method according to claim 210, wherein the viral vector is a replication-defective viral vector selected from the group consisting of adenovirus, herpes simplex virus, adeno-associated virus and retrovirus.

212. (New) A method of repairing or ameliorating sphincter muscle tissue injury, damage, or dysfunction associated with stress urinary incontinence, comprising:

- (a) providing a population of undifferentiated muscle-derived cells (MDCs) capable of giving rise to diverse muscle cell types and comprising an end population of cells isolated by a method comprising:
  - (i) plating a suspension of muscle cells in a first container to which fibroblast cells adhere;
  - (ii) re-plating non-adherent cells from step (a) in a second container when approximately 15-20% of the cells from the cell suspension have adhered to the first container;
  - (iii) repeating step (ii) at least two times to enrich for an end population of viable, non-fibroblast, desmin-expressing cells in the second container; and
  - (iv) isolating the MDCs as the end population of viable, non-fibroblast, desmin-expressing cells; and

(b) introducing the MDCs of step (a) into a site of the injured, damaged, or dysfunctional sphincter muscle tissue in an amount effective to repopulate, regenerate and repair the injured, damaged, or dysfunctional sphincter muscle tissue.

213. (New) The method according to claim 212, wherein the MDCs are autologous to a recipient in need of treatment.

214. (New) The method according to claim 212, wherein the MDCs are histocompatibly-matched with a recipient in need of treatment.

215. (New) The method according to claim 212, wherein the MDCs are obtained from skeletal muscle tissue or gastrocnemius muscle tissue.

216. (New) The method according to claim 212, wherein MDCs are introduced in an amount of about  $10^5$  to  $10^6$  cells per  $\text{cm}^3$  of tissue to be treated in a physiologically acceptable medium.

217. (New) The method according to claim 212, further comprising culturing the MDCs obtained according to step (a) under conditions allowing for their proliferation, differentiation, or a combination thereof, prior to said introducing step (b).

218. (New) The method according to claim 212, wherein a cloned population of the MDCs obtained in step (a) is introduced into a host in need of treatment.

219. (New) The method according to claim 212, further wherein subjecting the MDCs to a cytokine or growth factor selected from the group consisting of basic fibroblast growth factor (b-FGF), insulin-like growth factor (IGF), and nerve growth factor (NGF) prior to the introducing step (b) stimulates proliferation and myofiber fusion of the MDCs after introduction into the muscle tissue.

220. (New) The method according to claim 212, wherein the MDCs contain a heterologous polynucleotide encoding an IGF-1 cytokine or growth factor expressed by the MDCs.

221. (New) The method according to claim 220, wherein the MDCs are transduced with a viral vector containing the heterologous polynucleotide.

222. (New) The method according to claim 220, wherein the MDCs are transfected with plasmid DNA containing the heterologous polynucleotide.

223. (New) The method according to claim 221, wherein the viral vector is selected from the group consisting of adenovirus, herpes simplex virus, adeno-associated virus, and retrovirus.

224. (New) The method according to claim 219 or claim 220, further comprising introducing the same or different MDCs containing a heterologous polynucleotide encoding interleukin-1 receptor antagonist protein immune suppression factor (IRAP).

225. (New) The method according to claim 212, wherein the MDCs contain a vector containing a heterologous polynucleotide encoding human inducible nitric oxide synthase (iNOS), wherein the inducible nitric oxide synthase (iNOS) is expressed by the MDCs.

226. (New) The method according to claim 225, wherein the MDCs are transduced with a replication-defective viral vector containing the heterologous polynucleotide encoding inducible nitric oxide synthase (iNOS).

227. (New) The method according to claim 226, wherein the viral vector is a replication-defective viral vector selected from the group consisting of adenovirus, herpes simplex virus, adeno-associated virus and retrovirus.

228. (New) A method of repairing or ameliorating genitourinary tract tissue injury, damage, or dysfunction associated with stress urinary incontinence, comprising:
- (a) providing a population of undifferentiated muscle-derived cells (MDCs) capable of giving rise to diverse muscle cell types and comprising an end population of cells isolated by a method comprising:
    - (i) plating a suspension of muscle cells in a first container to which fibroblast cells adhere;
    - (ii) re-plating non-adherent cells from step (a) in a second container when approximately 15-20% of the cells from the cell suspension have adhered to the first container;
    - (iii) repeating step (ii) at least two times to enrich for an end population of viable, non-fibroblast, desmin-expressing cells in the second container; and
    - (iv) isolating the MDCs as the end population of viable, non-fibroblast, desmin-expressing cells; and
  - (b) introducing the MDCs of step (a) into a site of injured, damaged, or dysfunctional genitourinary tract tissue selected from sphincter or urethra muscle tissue, or a combination thereof, in an amount effective to repopulate and repair the injured, damaged, or dysfunctional genitourinary tract tissue.
229. (New) The method according to claim 228, wherein the MDCs are autologous to a recipient in need of treatment.
230. (New) The method according to claim 228, wherein the MDCs are histocompatibly-matched with a recipient in need of treatment.
231. (New) The method according to claim 228, wherein the MDCs are obtained from skeletal muscle tissue or gastrocnemius muscle tissue.

232. (New) The method according to claim 228, wherein MDCs are introduced in an amount of about  $10^5$  to  $10^6$  cells per  $\text{cm}^3$  of tissue to be treated in a physiologically acceptable medium.

233. (New) The method according to claim 228, further comprising culturing the MDCs obtained according to step (a) under conditions allowing for their proliferation, differentiation, or a combination thereof, prior to said introducing step (b).

234. (New) The method according to claim 228, wherein a cloned population of the MDCs obtained in step (a) is introduced into a host in need of treatment.

235. (New) The method according to claim 228, further wherein, subjecting the MDCs to a cytokine or growth factor selected from the group consisting of basic fibroblast growth factor (b-FGF), insulin-like growth factor (IGF), and nerve growth factor (NGF) prior to the introducing step (b) stimulates proliferation and myofiber fusion of the MDCs after introduction into the muscle tissue.

236. (New) The method according to claim 228, wherein the MDCs contain a heterologous polynucleotide encoding an IGF-1 cytokine or growth factor expressed by the MDCs.

237. (New) The method according to claim 236, wherein the MDCs are transduced with a viral vector containing the heterologous polynucleotide.

238. (New) The method according to claim 236, wherein the MDCs are transfected with plasmid DNA containing the heterologous polynucleotide.

239. (New) The method according to claim 237, wherein the viral vector is selected from the group consisting of adenovirus, herpes simplex virus, adeno-associated virus, and retrovirus.

240. (New) The method according to claim 235 or claim 236, further comprising introducing the same or different MDCs containing a heterologous

polynucleotide encoding interleukin-1 receptor antagonist protein immune suppression factor (IRAP).

241. (New) The method according to claim 228, wherein the MDCs contain a vector containing a heterologous polynucleotide encoding human inducible nitric oxide synthase (iNOS), wherein the inducible nitric oxide synthase (iNOS) is expressed by the MDCs.

242. (New) The method according to claim 228, wherein the MDCs are transduced with a replication-defective viral vector containing the heterologous polynucleotide encoding inducible nitric oxide synthase (iNOS).

243. (New) The method according to claim 242, wherein the viral vector is a replication-defective viral vector selected from the group consisting of adenovirus, herpes simplex virus, adeno-associated virus and retrovirus.

244. (New) A method of repairing or ameliorating injured, damaged, or dysfunctional bladder contractility associated with stress urinary incontinence, comprising:

- (a) providing a population of undifferentiated muscle-derived cells (MDCs) capable of giving rise to diverse muscle cell types and comprising an end population of cells isolated by a method comprising:
  - (i) plating a suspension of muscle cells in a first container to which fibroblast cells adhere;
  - (ii) re-plating non-adherent cells from step (a) in a second container when approximately 15-20% of the cells from the cell suspension have adhered to the first container;
  - (iii) repeating step (ii) at least two times to enrich for an end population of viable, non-fibroblast, desmin-expressing cells in the second container; and



- (iv) isolating the MDCs as the end population of viable, non-fibroblast, desmin-expressing cells; and
- (b) introducing the MDCs of step (a) into a site of the bladder or detrusor muscle wall in an amount effective to repopulate the site of bladder or detrusor muscle to repair the injured, damaged, or dysfunctional bladder contractility.

245. (New) The method according to claim 244, wherein the MDCs are autologous to a recipient in need of treatment.

246. (New) The method according to claim 244, wherein the MDCs are histocompatibly-matched with a recipient in need of treatment.

247. (New) The method according to claim 244, wherein the MDCs are obtained from skeletal muscle tissue or gastrocnemius muscle tissue.

248. (New) The method according to claim 244, wherein MDCs are introduced in an amount of about  $10^5$  to  $10^6$  cells per  $\text{cm}^3$  of tissue to be treated in a physiologically acceptable medium.

249. (New) The method according to claim 244, further comprising culturing the MDCs obtained according to step (a) under conditions allowing for their proliferation, differentiation, or a combination thereof, prior to said introducing step (b).

250. (New) The method according to claim 244, wherein a cloned population of the MDCs obtained in step (a) is introduced into a recipient in need of treatment.

251. (New) The method according to claim 244, further wherein, subjecting the MDCs to a cytokine or growth factor selected from the group consisting of basic fibroblast growth factor (b-FGF), insulin-like growth factor (IGF), and nerve growth factor (NGF) prior to the introducing step (b) stimulates proliferation and myofiber fusion of the MDCs after introduction into the muscle tissue.

252. (New) The method according to claim 244, wherein the MDCs contain a heterologous polynucleotide encoding an IGF-1 cytokine or growth factor expressed by the MDCs.

253. (New) The method according to claim 252, wherein the MDCs are transduced with a viral vector containing the heterologous polynucleotide.

254. (New) The method according to claim 252, wherein the MDCs are transfected with plasmid DNA containing the heterologous polynucleotide.

255. (New) The method according to claim 253, wherein the viral vector is selected from the group consisting of adenovirus, herpes simplex virus, adeno-associated virus, and retrovirus.

256. (New) The method according to claim 251 or claim 252, further comprising introducing the same or different MDCs containing a heterologous polynucleotide encoding interleukin-1 receptor antagonist protein immune suppression factor (IRAP).

257. (New) The method according to claim 244, wherein the MDCs contain a vector containing a heterologous polynucleotide encoding human inducible nitric oxide synthase (iNOS), wherein the inducible nitric oxide synthase (iNOS) is expressed by the MDCs.

258. (New) The method according to claim 257, wherein the MDCs are transduced with a replication-defective viral vector containing the heterologous polynucleotide encoding inducible nitric oxide synthase (iNOS).

259. (New) The method according to claim 258, wherein the viral vector is a replication-defective viral vector selected from the group consisting of adenovirus, herpes simplex virus, adeno-associated virus and retrovirus.